

Remarks

Claims 1-3, 5-8, 11, 12, 15-17, 19 and 20, are pending.

Applicants traverse the rejections maintained in the Advisory Action on the grounds that a well-established utility is recited in the application as filed, the steps for achieving this utility are taught in the application, and the recited utility is validated by data.

A well-established utility taught in the application is the treatment of depression. This utility is disclosed at page 8, lines 7-8. The Office has admitted that this is an asserted utility (Advisory Action, sentence bridging pages 2 and 3). However, the Advisory Action states that the application does not teach how carry out a disclosed utility.

The in vivo data presented show reduction in melatonin levels, but they do not directly show an increase in serotonin in the brain. However, based on the well-known relationship of serotonin as a precursor of melatonin, one would conclude that reducing melatonin production by the disclosed and exemplified mechanism necessarily indicates increased levels of serotonin because the methods used block the activity of an enzyme that converts serotonin to a precursor of melatonin (see description of chemical synthesis and biosynthesis of melatonin (pp. 3 and 4 of 5) from the web page of the Department of Chemistry of the Imperial College of London, attached as Exhibit 1). Thus, the data provide strong and uncontroverted evidence that the present methods increase serotonin in the brain.

It is well-established that decreased serotonin causes depression. It is equally accepted that increasing serotonin treats depression (Mann JJ. The medical management

of depression. N Engl J Med. 2005 353:1819-34, attached as Exhibit 2). There is no objective reason, known to applicants or stated by the Office, to doubt that increasing serotonin in the brain (as demonstrated by applicants) would treat depression. In the absence of any such objective evidence, the Office must accept applicant's teaching that the present methods can be used to treat depression (In re Marzocchi, 439 F.2d 220, 169 USPQ 367 (CCPA 1971); initially, the Patent Office must accept the objective truth of statements made in the specification. If such statements are to be called into question, the Patent Office is burdened with providing evidence or convincing argument why those of skill in the art would doubt the statements).

The application teaches the steps for increasing serotonin in the brain to treat depression. Particularly, a patient diagnosed with depression can be treated by administration of an alkylating derivative of an acetyl acceptor substrate of AANAT in a dosage range of about 1 to 10 mg/kg of body weight, 1 to 4 times per day (specification, page 11). The effectiveness of an alkylating derivative of an acetyl acceptor substrate of AANAT at increasing serotonin in the prescribed dosage range is confirmed in Exhibit C to the Response filed January 2, 2003. The application has many further examples of guidance for the skilled person to assist in the practice of the claimed invention. These have been described in detail in the previous responses. Thus, no undue experimentation would be required to practice a disclosed credible, specific and substantial utility, e.g., treating depression.

In conclusion, there is no basis to doubt the role of serotonin in depression or the ability of the steps taught to increase serotonin levels in the brain. Thus, there is no basis to believe that the present application fails to show how to use the present invention to

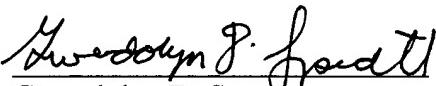
treat depression. Having enabled a specific credible use for each claim, claims 1-3, 5-8, 11, 12, 15-17, 19 and 20, are enabled.

Pursuant to the above remarks, reconsideration and allowance of the pending application is believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of the application to issue.

A Credit Card Payment Form PTO-2038 authorizing payment in the amount of \$2,380.00 representing the fee for a large entity under 37 C.F.R. § 1.114 (\$790.00), Request for Continued Examination (RCE) and a Request for Extension of Time (1.17(a)(4) (\$1590.00) are enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

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CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence, including any items indicated as attached or included, is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.

Gwendolyn D. Spratt
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11-30-05
Date